Report-**Dextrin-Accession #246-Cas. Reg. #PM9004539 & Corn Dextrin-Accession #247-Cas. Reg. #977050013** 1/18/74

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FOOD AND DRUG
Research LABORATORIES, INC.

R E P O R T

DFXTRIN
ACCFSSION NO. 246
CAS. REG. NO. PM9004539

AND

CORN DFXTRIN
ACCESSION NO. 247
CAS. REG. NO. 977050013

Submitted to:
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Bureau of Foods
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SUMMARY

"Starch conversions" are essentially processes for reducing the viscosity of raw starch by degradative attack on the starch molecules. Such conversions permit the use of efficient low cost techniques which are suited for the manufacture of products which can be recovered with the granule still intact and sold in dry form. In these conversions white dextrins, yellow dextrins and British gums are produced. Yellow dextrins are made with moderately high amounts of acid, low moisture and fairly high converting temperatures. All yellow dextrins are low in viscosity and essentially are completely soluble in cold water. In conversion of white dextrins, hydrolysis is the dominant reaction. Moisture, high acidity and relatively low converting temperatures are used in their preparation. White dextrins display a wide range of viscosities and cold water solubility depending upon the degree of conversion. Little or no acid and, in some cases, buffers and high temperatures characterize British gum conversions. British gums are not as low in viscosity as yellow dextrins or the thinnest white dextrins, and in addition, are much more stable than white dextrins in solution (302).

The dextrins have a wide variety of uses as excipients for dry extracts and pills, for preparing emulsions and dry bandages, for thickening dye paste and mordants used in printing fabrics in fast colors. Other uses include sizing paper and fabrics, printing tapestries, preparing felt, manufacturing printer's ink, glues and mucilage, polishing

cereals, in matches, fireworks and explosives and, quite often, as the carbohydrate source in animal feeds (304).

The toxicity of iron dextrin intravenously administered to mice was significantly increased during pregnancy. The LD_{50} was found to be 446 (350 - 569) mg/fe/kg in the non-pregnant animals but 127 (94.4 - 171) mg/fe/kg in pregnant mice medicated on the 13th day of gestation (23a).

Corn dextrin diets caused a slight diarrhea and cecal enlargement in rats and the protein deficiency value was significantly poorer than the values obtained for unmodified starch (299).

Incorporation of riboflavin in a diet containing a high amount of dextrin increased the growth rate in rats, while diets that were high in fat + dextrin, but deficient in riboflavin, caused paralysis of the hind quarters (167).

Rats fed a diet containing a high level of sucrose developed dermatitis and had a poor growth rate, whereas those fed rations containing dextrin showed no dermatitis and had a much higher growth rate. Further, an increased growth rate was found in several species fed diets containing dextrin as compared to animals which were fed diets containing another carbohydrate source (24, 180, 42, 143, 289).

Other studies revealed that animals fed diets containing dextrin had a much superior performance in protein repletion and nitrogen balance than animals fed diets containing sucrose or other sources of carbohydrates (81, 44, 22, 23, 179).

In other short-term studies, it was shown that nitrogen equilibrium was achieved in rats fed protein depleted or undepleted rations containing corn dextrin. When 1% sulfasuxidine was supplemented in the diet, additional improvement in the nitrogen balances was observed (171).

The levels of hepatic triglycerides were found to be much higher in rats fed sucrose-containing diets than those fed dextrin-containing diets (42, 43).

The anaphylactoid activity of intraperitoneally-injected dextrin in rats was inversely proportional to the time of hydrolysis, and very large amounts of glucose were required to antagonize the responses produced by dextrin (115).

Experiments in which rabbits were injected intravenously with tapioca dextrin for varying numbers of doses, demonstrated that dextrin was not a source of high caloric intake. Histopathology of these animals revealed hydropic degeneration in the epithelium of the proximal convuluted tubules of the kidneys, which were found to be reversible during an oral feeding recovery period (71).

In another short-term rat study, a number of compounds were studied for their nutritive value. Nutritive value indices showed that the most effective were polysaccharides, dysaccharides, and maltose, followed by starch and dextrin. Many of the materials tested were found to be far inferior to this group and agar agar was entirely invalid (13).

In young puppies fed diets containing sucrose, a dextri-maltose or corn syrup as the carbohydrate, it was found that each was equally suitable as a dietary carbohydrate (289).

A comparative study of dextrose and dextrin tolerance was conducted in patients with chronic ulcerative colitis. It was found that a dextrin preparation maintained significantly higher blood dextrose levels for three hours than did dextrose. This led to the assumption by the investigators that, in these patients, dextrin was better absorbed from the intestine than was dextrose (208).

DEXTRINS

Chemical Information

I. Nomenclature

A. Common Names

Corn dextrin

No other common names were encountered in the literature searched.

Dextrin

British gum, starch gum, gommelin

B. Chemical Names

Corn dextrin

No other chemical names were encountered in the literature searched.

Dextrin

No other chemical names were encountered in the litera- searched.

C. Trade Names (304)

Corn dextrin

No trade names were encountered in the literature searched.

Dextrin

Fortodex, Leiocom

D. Chemical Abstracts Unique Registry Number

Corn dextrin

977050 - 01 - 3

Dextrin

PM9004 - 53 -9

II. Empirical Formula (304)

Corn dextrin

No empirical formula was encountered in the literature searched.

Dextrin

$(C_6H_{10}O_5)_n.xH_2O$

III. Structural Formula

Corn dextrin

No structural formula was encountered in the literature searched.

Dextrin

No structural formula was encountered in the literature searched.

IV. Molecular Weight

Corn dextrin

No molecular weight was encountered in the literature searched.

Dextrin

No molecular weight was encountered in the literature searched.

V. Specifications

A. Chemical

Corn dextrin

No chemical specifications were encountered in the literature searched.

Dextrin

No chemical specifications were encountered in the literature searched.

B. Food grade

Corn dextrin

No food grade specifications were encountered in the literature searched.

Dextrin

No food grade specifications were encountered in the literature searched.

VI. Description

A. General characteristics (304)

Corn dextrin

No general characteristics were encountered in the literature searched.

Dextrin

Produced by the incomplete hydrolysis of starch with dil acids, or by heating dry starch. White or yellow, amorphous powder. The white is practically odorless; the yellow has a characteristic odor.

B. Physical properties (304)

Corn dextrin

No physical properties were encountered in the literature searched.

Dextrin

It is dextrorotatory. $[\alpha]_D$ generally above 200 . Soluble in 3 parts boiling water to a gummy soln; less sol in cold water; insol in alcohol and ether. Does not reduce Fehling's soln; give a reddish-brown color with iodine.

C. Stability in containers

Corn dextrin

No stabilities were encountered in the literature searched.

Dextrin

No stabilities were encountered in the literature searched.

VII. Analytical Methods

No analytical methods for corn dextrin or dextrin were encountered in the literature searched.

VIII. Occurrences and Levels (303)

A. Plants

Corn dextrin

No occurrences or levels in plants were encountered in the literature searched.

Dextrin

Pecan kernel, coconut meal, English walnut, European chestnuts, chufa, ivory nut, raw starch.

B. Animals

Corn dextrin

No occurrences or levels for animals were encountered in the literature searched.

Dextrin

No occurrences or levels in animals were encountered in the literature searched.

C. Synthetics

Corn dextrin

No occurrences or levels in synthetics were encountered in the literature searched.

Dextrin

No occurrences or levels in synthetics were encountered in the literature searched.

D. Natural Inorganic sources

Corn dextrin

No occurrences and levels in natural inorganic sources were encountered in the literature searched.

Dextrin

No occurrences or levels in natural inorganic sources were encountered in the literature searched.

The influence of pregnancy on the acute toxicity of various compounds in Charles River, CD-1 female mice was studied. All animals were medicated intravenously on the 13th day of gestation, and the LD_{50} value of iron dextrins was reported as mg/kg of iron. In non-pregnant female mice, it was found to be 446 (350-569) mg/fe/kg. The LD_{50} computed at 4 days post-dose of the iron dextrin was 127 (94.4-171) mg/fe/kg. It can be seen that 4 day post-dose values were not significantly different between non-pregnant animals and 4 day pregnant animals, but there was a statistically significant difference at the 7th day period between non-pregnant and pregnant mice (23a).

The utilization of various starches and sugars was studied in the male Wistar rat, weighing 50 - 55 g, to determine the dietary effect of carbohydrate on the utilization of protein. All diets were fed ad libitum to 10 animals per dose level for 28 consecutive days. Unmodified corn starch was used as a control because this carbohydrate had been cited frequently in the literature as a normal control. Corn dextrin diets caused a slight diarrhea and ceca which were about twice the weight of those obtained with unmodified corn starch. The protein efficiency value obtained from the corn dextrin diet was significantly poorer than the value obtained for unmodified corn starch at a dietary level of 15%. Corn dextrin in combination with 6% protein or 15% protein had no untoward effect on liver weight and liver fat content. As reported by this author, the same results as shown in the first study were found in another study using 9 and 15% levels of dietary proteins. Again, the unmodified corn starch did not produce enlarged ceca, while corn dextrin did (299).

A study was undertaken to determine the relationship between dietary dextrin and riboflavin and to determine the effects of other carbohydrates and fat on the requirement for fecal excretion of riboflavin. Male rats, ranging in weight from 35 - 40 g were fed ad libitum diets containing various carbohydrates for a period of three weeks. 0, 3, 6, 9, and 12 micrograms/day of riboflavin were incorporated into the various diets. At each level of riboflavin intake, the growth of the animals receiving a high dextrin ration was superior to that of rats fed a 40% fat diet. Another study demonstrated that a high fat dextrin diet, deficient in riboflavin, caused plasticity and paralysis of the hind quarters. This condition did not occur with any marked severity when a high dextrin ration alone was fed (167).

A diet containing 62 parts dextrin was fed to rats to determine the influence of dextrin and sucrose on growth and dermatitis. Of two diets studied, the primary modification was the replacement of the 62 parts dextrin by sucrose. A significant reaction, found in almost all of the animals receiving sucrose rations, was the development of dermatitis. Comparative data from the basal ration containing dextrin and sucrose showed that no dermatitis resulted when dextrin was the carbohydrate. When these diets were supplemented with vitamin B_1 and lactoflavin, the dermatitis was not prevented in the animals fed the sucrose diets. These supplements permitted normal growth in the sucrose group, and promoted a substantial increase in rate of growth in animals given dextrins (24).

Chickens which were a cross between New Hampshire male and single comb white leghorn females were fed a diet which contained 60.2 g of carbohydrate/100 g diet for 4 weeks. 65 animals/dose level were allowed the diet ad libitum. The purpose of this study was to determine the effect of dietary protein on the growth of chicks fed purified diets containing sucrose or dextrin. Four representative experiments of a total of nine are presented. In experiment 1, various levels of casein were fed to groups of chicks receiving either sucrose or dextrin diets. When the level of casein in the diet was 18% or less, each group that received dextrin as a carbohydrate grew more rapidly than the sucrose control. The greatest difference between the two groups occurred when the chicks were fed a level of 18% casein. When the level of casein was increased to 22%, no appreciable difference in growth occurred. In the second experiment, the group fed the 22% grew faster than those receiving the 18% casein sucrose. In this study, many of the dextrin and sucrose group variances were magnified because of the presence of one or two excessively heavy chickens. In the negative control group, the variances were frequently exaggerated by the presence of a few birds considerably below average (180).

A feeding study was conducted with chicks from New Hampshire males crossed with single comb white leghorn females. The chicks were one-day-old at the start of the 4-week experiment. The various carbohydrates were administered to 12 chicks/group ad libitum in a diet in which 61 g of the diet was carbohydrate. All chicks in the dextrin group survived the four-week duration of the study. The chicks receiving the basal ration containing dextrin demonstrated a 73 g body weight increase relative to those receiving sucrose. The feathering and general appearance of the birds receiving dextrin was excellent. When folic acid was added to the basal ration, there was a very significant decrease in growth in all diet groups containing casein, but the birds receiving dextrin continued to show the best growth rate. This study revealed that the chick has a smaller requirement for folic acid on a ration containing dextrin than when dextrin is replaced by another carbohydrate source. Sulfasuxidine, fed to chicks on the different carbohydrates, caused a retardation of growth in contrast to no effect among the dextrin-fed birds. This indicates that the intestinal flora established on a ration containing dextrin as the carbohydrate constituent is affected in a different way, and to a different extent, by sulfasuxidine than the flora of chicks fed other carbohydrates. The excretion time of carbohydrates lactose, sucrose and dextrin by chicks was also studied in this experiment. The excretion times for dextrin, measured at 2 and 4 weeks, were 20% longer than for sucrose. This data lends support to the theory that carbohydrate differences may be explained on the basis of intestinal synthesis or efficiency of carbohydrate breakdown in the gut. It seems that dextrin allows more time for synthesis to take place since chicks fed this ration retained the food longer (179).

150 ml/day of Anhydrase glucose solutions containing tapioca dextrin were administered intravenously to male and female rabbits weighing approximately 2.1 kg, for a period of 11 days. The purpose of this study

was to determine the tolerance, toxicity and caloric availability of intravenously injected tapioca dextrin solutions. At the termination of the study, sections of kidney, spleen, liver, lung, pancreas, adrenal and muscle were taken, sliced, and stained with hemotoxylin and eosin for histological examination. The liver and kidneys were also stained with Best's carmine for glycogen. The chemical constituent of a 36% tapioca dextrin solution is given in Exhibit 1.* Infusion of 150 ml of solution (at a rate of 55 cc/hour) resulted in death on the 9th day. Prior to death, the animals were too weak to stand, had an unkempt appearance, and the abdomen was distended, tense and tender. The animals appeared to be in a stupor. Disturbance of the animals caused intermittent tonic and chronic convulsions that progressed until death. Post-mortem examination showed edematous abdominal skin, muscles and viscera which contained an abnormal amount of straw-colored protein-containing fluid in pleural and peritoneal cavities. Histological examinations of the lung and spleen were normal. Individual liver cells were generally pale and contained small vacuoles. There was a marked generalized swelling of the tubular epithelium of the kidney. The vacuoles in the kidney and liver sections did not contain glycogen. However, when the animals were administered 150 ml of the solution in 2-3 hour injection periods, the majority of the animals tolerated these repeated daily infusions, although steady decrease in body weight was observed. Two of 12 animals developed the previously described chronic toxic symptoms (71).

Several studies, ranging from 2 to 12 weeks in duration, were done

* See page 40.

on male Sprague-Dawley rats to determine the influence of various carbohydrates on the utilization of low protein rations. The animals were 40 to 50 g at the start of the experiment and, in most studies, were provided the designated diets ad libitum. The major composition of the basal diet was 81.6% sucrose and 9% casein. Supplements to this diet were at the expense of the carbohydrate. In the several studies presented, dextrin provided better growth rate than sucrose, regardless of whether the protein in the diet was supplied as casein, egg albumin or wheat gluten, or whether a mixture of amino acids simulating casein was used. The liver fat of rats fed low casein diets or amino acids of similar composition was reduced when the sucrose in the diet was replaced by dextrin. The implication of these results suggests that there is improved utilization of dietary protein when sucrose in low protein diets is replaced by dextrin (113).

In several studies varying in duration, male rats were fed various carbohydrate-containing diets utilizing sucrose, agar agar, inulin, dextrin, sacrose, maltose, and lactose. These studies were done in an attempt to determine the relative value of various carbohydrates. In relative value in reference to weight gain of the materials studied, dextrin was the 3rd best. In one of the studies in which dextrin was used as the control, dextrin rated 4th behind fructose, glucose and starch in the amount of weight gain provided per day. In another study, dextrin was not included, but, when the previous body weights obtained were compared, the figures from other studies showed that the dextrin-fed group gained more on a g/day basis than any of the animals fed the other compounds used. During one of the studies, urine was collected for 18 hours after the injection of carbohydrate and was tested qualitatively for reducing substances. Urine from the dextrin-fed animals had no reducing power (13).

The effects of different dietary carbohydrates fed for 18 months were studied in male Sprague-Dawley rats beginning at 2 months of age. Food consumption was done on the assumption that each animal consumed 20 g/day of a diet which contained 4 g of dextrin. The weight and food consumption were used to calculate the protein efficiency ratio (the ratio of the g of body weight gain to g of proteins consumed over a six-month period). At the end of 18 months, animals fed 20 g of the diet containing 4 g of dextrin showed a much greater weight gain than those animals receiving a diet of regular laboratory chow. Serum cholesterol determinations were made after 9, 14, and 18 months of feeding. At the 9 and 18 month periods, total serum fatty acids were also determined. The values for serum cholesterol and total fatty acids in both the dextrin and chow-fed animals were comparable at each interval. Both groups in the two parameters studied showed a marked increase in values with age between 9 and 18 months. The mean water consumption and output of stool/day/100 g for each group of rats was determined. The relationship of water consumption, dried stool residue, and weight gain demonstrated that animals fed a diet containing dextrin had a better weight gain and better protein efficiency ratio than those animals fed regular laboratory chow. Animals were sacrificed terminally with ether, and the liver, testes, epididymis, and fat pads were removed, trimmed and weighed. The difference in liver weight between animals fed dextrin and those fed regular laboratory chow was not statistically significant, while the increased testicular weight was found to be statistically significant. In the studies reported, there were no significant toxicological findings among rats fed a diet containing 4 g of dextrin/day or those fed regular laboratory chow (49).

Male Sprague-Dawley rats were fed a series of diets, ad libitum for periods varying from 4 to 10 weeks in an attempt to determine the effects of carbohydrates on the utilization of protein and lysine. Series 1 was a diet without lysine, and Series 2 was a diet supplemented with lysine. The average body weight increase of rats fed the different carbohydrate diets without lysine supplement was lower for those rats fed sucrose than for those fed dextrin. All groups, regardless of the source of carbohydrate, exhibited a better growth rate when the diet was supplemented with lysine. When lysine-supplemented diets containing dextrin were fed, the protein efficiency ratio was greatly enhanced. The fecal food nitrogen and metabolic nitrogen excreted by rats fed dextrin was about 1/2 that of those fed raw potato starch but twice as much as rats in some of the other groups. This indicated that the digestibility of the protein in the dextrin diet was very low. It was found that the lysine availability in rats fed dextrin diets was higher than that of some of the other groups but lower than those fed corn starch, sucrose and glucose diets (44).

Weanling male Sprague-Dawley rats were fed diets containing various carbohydrates in an attempt to determine the relation of amino acid imbalance to niacin -trytophane deficiency. In this study very little emphasis was placed on the dextrin diet, but again, as in other studies reported in this review, in all cases the dextrin rations produced markedly superior growth rates compared to sucrose rations (143).

Twelve experimental diets, prepared to simulate infant formulas, were fed to dogs 6 to 9 weeks old for varying lengths of time. This study was designed to determine the lipid metabolism of puppies as affected by time and amount of fat and dietary carbohydrate. There were 4 low-fat basal diets which were considered to be adequate in calories, proteins, vitamins and minerals. The carbohydrates studied were lactose, sucrose, dextri-maltose and corn syrup. There was one death during the first 12 weeks of life in the group of animals fed dextri-maltose. Sucrose, dextri-maltose and corn syrup were equally acceptable as a source of carbohydrate among groups fed the same diet. There were no consistent trends in rate of growth attributed to either of these diets. Histologically, desquamation of the skin was found and was similar whether the carbohydrate was sucrose, dextri-maltose, or corn syrup whenever the diets were deficient in linoleic acid. Diets which were not deficient in linoleic acid did not cause any histological differences attributed to the types of carbohydrates. The total serum protein did not show any significant variations for mean serum protein levels. The mean values for reducing sugars in the urine of dogs receiving sucrose, dextri-maltose, and corn syrup were low, although sugars were present in all urines. When dextri-maltose was fed, lactose appeared in nearly all urine and galactose in 45% of the specimens. In these specimens, metabolic responses to sucrose, dextri-maltose or corn syrup did not show consistent trends when the intake of the fat was the same. It differed only when lactose was fed. The authors conclude that in growing puppies dietary fat affects the level and composition of serum lipids to a greater extent than does the dietary carbohydrate (287).

To determine the influence of different types of carbohydrates on the progress of protein depletion and repletion in rats, male and female animals weighing 120 - 130 g were fed a diet containing mineral mixture - 4 g, refined arachis oil - 9 g, vitamin mixture - 2 g, choline chloride- .2 g, and carbohydrate - 9.5 to 100 g. Records were maintained of the daily food consumption and bi-weekly body weight, and urine and stool collections were made. Near the end of the study, a few animals were sacrificed and tissue weight, carcass nitrogen, glucose, pyruvic acid in the blood, and glycogen activity of certain enzymes in the liver were determined. Animals not sacrificed were maintained on the diet supplemented with casein protein at 18% level for an additional 21 days. There was no significant difference in the relative weights of the adrenal, kidney, and spleen as a result of feeding the different diets, but the relative liver weight was higher in the groups fed sucrose than in groups fed other carbohydrates. The pancreas weight increased in all groups during the protein depletion period. The body weight changes and nitrogen metabolism during the depletion period decreased, and the decrease in body weight was greater in the sucrose-fed group than in the corn starch-fed group. There was a higher rate of endogenous nitrogen excretion and a greater loss of carcass nitrogen in the sucrose group. Animals fed corn starch and dextrin did not show as much weight loss in nitrogen retention as did other carbohydrates. These findings were indicative of the protective influence of corn starch and dextrin. After protein repletion, the corn starch and dextrin groups regained the activity of all the liver enzymes except a lower value of xanthine oxidase was indicated in the sucrose-fed animals. Pancreatic amylase activity was found to be low in all groups with the sucrose-fed group again having the lowest value. Protein feedings significantly raised the enzyme activity except in sucrose-fed animals in which the normal amylase activity was not regained. A significant decrease in fasting glucose levels and a slight rise in blood pyruvic acid level were found in all groups during protein depletion. Both liver glycogen and liver fat tended to increase, and the increase was highest in sucrose-fed animals (81).

The influence on carbohydrates, nitrogen source and prior state of nutrition on nitrogen balance and liver composition was studied in adult rats. Animals fed 0.1% of the essential amino acid with sucrose as the carbohydrate had more of a negative nitrogen balance and a greater accumulation of fat in the liver than animals fed the same quantities of amino acids supplemented with corn dextrin. Glutamic acid fed at a level of 1.65% significantly improved the nitrogen balance of the animals fed sucrose, but it was without effect on corn dextrin-fed animals.

Levels as high as 6.5% glutamic acid did not have any effect on the nitrogen balance of animals fed corn dextrin diets. The livers of animals fed sucrose, except for a protein-free diet, contained more protein than those of corresponding animals fed corn dextrin diets. The authors believe that these findings suggest that corn dextrin in the diet facilitates the use of preformed liver protein or amino acids (298).

Male Wistar rats weighing 86 to 104 g were fed a diet of dextrin or sucrose for periods ranging from 3 to 8 days. This was in an attempt to determine the lipotrophic effect of dextrin vs sucrose in choline-deficient rats. At the end of an adjustment period, animals were assigned to 4 groups and fed diets which contained sucrose or dextrin as the carbohydrate source. In the case of each of these semi-synthetic diets, one was choline-deficient and the second choline-supplemented. All animals were sacrificed one day following either the 3 or 8 day dietary regimen. The livers of animals fed the choline-deficient sucrose diet were heavier and contained more fat than those of their dextrin-fed counterparts. This difference was observed despite the fact that the later group had consumed more food than the former at the end of 8 days. This study demonstrates that by manipulating the composition of the diets and the environment to which the choline deficient rats were subjected, it is possible to alter the level of lipids that accumulate within the hepatic cells. There was a reduction in hepatic triglycerides upon substitution of sucrose by dextrin in the choline deficient diet (42).

Male Wistar rats, weighing 170 to 220 g, were kept on a choline-deficient diet for 4 days and sacrificed on day 5. This experiment was a further study on the partial lipotrophic effect of dextrin in choline-deficient rats. Seven feeding studies were conducted, and body weight, food intake, cecal volume and hepatic triglyceride levels were determined. Differences in the levels of hepatic triglycerides between the sucrose and dextrin-fed choline-deficient animals persisted despite various dietary modifications. In an attempt to abolish this difference, the diets in experiment No. 7 were supplemented with 1% sulfaguanidine. Although the levels of hepatic triglycerides were higher in the sucrose-fed rats than in their dextrin-fed counterparts, the differences between the two groups were not statistically significant. The authors surmised that dextrin may decrease the choline requirements of rats by altering the intestinal bacterial flora. Supplementation of the diets with neomycin sulfate or sulfaguanidine did not eliminate the difference in hepatic triglyceride levels between the two groups. This study confirmed the findings in the previous study which is reviewed in the above paragraph. The growth of the dextrin-fed animals was much greater than that of the sucrose fed animals and the liver triglycerides were much less in the dextrin group (43).

In another study, similar to the two reviewed in the preceding paragraphs, the effect of factors other than choline on liver fat deposition was studied. Three-week-old male Sprague Dawley rats were fed diets containing various sources of carbohydrates, of which one was dextrin, ad libitum for 5 weeks. Terminally, livers were taken and the fat content measured. The animals on the dextrin basal ration showed a higher growth rate even without addition of niacin or tryptophane, and the deposition of liver fat was not as extensive as in the sucrose group. When 6% gelatin was added to the basal dextrin diet, a decrease in liver lipids and growth weight was observed. Supplements of either tryptophane or niacin together with gelatin completely inhibited the apparent growth antagonism precipitated by the gelatin and maintained the liver fat at low levels. The authors surmised that the difference in the carbohydrates may be in the rate of passage through the gut, the dextrin diet taking longer to pass through, therefore affording a longer period for digestion and absorption (156).

Sprague-Dawley and/or Osborne Mendal rats weighing 40 to 50 g were used in a study of the influence of fructose and other carbohydrates on the niacin content of liver and thigh muscles in which urinary n'-methylnicotinamide determinations were done. Niacin deficiency developed in the animals by feeding sucrose-containing rations for 7 to 14 days. Various experimental diets were prepared by substituting the designated carbohydrate in the basal diet. There was a wide difference in growth between the various carbohydrate diets. Starch and dextrin provided relatively good growth rates and seemed to produce a rather mild niacin deficiency (124).

Serum electroproesis in rats fed various carbohydrate diets was done in an attempt to determine if there was an alteration in the serum protein patterns. Male Sprague-Dawley rats weighing 70 to 80 g were fed various diets containing carbohydrates ad libitum for a period of 12 weeks. Two series of each diet were studied: one in which the basic diet did not contain L-lysine and another in which 0.7% L-lysine was added. Five serum protein fractions designated as albumin and alpha-1, alpha-2, beta and gamma globulins were separated. Rats fed either raw or cooked potato starch exhibited significantly lower total serum protein levels than those which received corn starch, glucose or dextrin. Lysine supplementation increased the total serum protein regardless of the carbohydrate source. In all cases except when the carbohydrate was potato starch or dextrin, alpha-1 protein level was increased (45).

Three series of studies were conducted in male rats ranging in age from 70 to 79, 91 to 106, or 90 to 100 days to determine some factors affecting nitrogen balance. Diets were provided ad libitum, and urine and feces were collected. The differences observed between animals receiving glucose or potato dextrin were significant but were overshadowed by the much greater improvement brought about by a change to corn dextrin. The difference between the nitrogen balance in animals receiving sucrose or potato dextrin at the high levels of amino acids was not significant, while the change to corn dextrin resulted in a significant improvement. In the fecal nitrogen excretion of the animals ingesting dextrin-containing rations, there was an average of 1.4 to 3.5 mg/day more fecal nitrogen then in animals receiving diets containing sucrose. Animals receiving potato dextrin showed an increase in fecal nitrogen excretion which was considerably higher than the increase in nitrogen intake. Substituting dextrin made from either corn starch or potato starch supported growth at a rate equivalent to that resulting from the addition of corn starch alone. The feeding of 1% sulfasuxidine with the corn dextrin brought about an additional improvement in nitrogen balances (171).

The effect of amino acid imbalance on low fibrin diets was studied in male Sprague-Dawley rats weighing 40 to 50 g at the beginning of the study and fed the designated diet ad libitum for a period of 2 weeks. The basal diet used consisted of 6% fibrin, 5% corn oil, 4% salts, 25% vitamin mixture, .15% choline chloride, and supplements of various amino acids and sucrose or dextrin. It was found that when dextrin replaced sucrose in the diet, growth rate was substantially improved, but the effects of various amino acid supplements on growth and fat deposition were similar to those findings in the sucrose group. The findings here were similar to several of the studies reviewed above in which it was observed that protein requirement expressed as the percentage of the diet is greater when sucrose, rather than dextrin, is the dietary carbohydrate (70).

To determine the influence of dietary carbohydrate on levels of amino acid in the feces, a study was conducted with male Wistar rats weighing 40 to 50 g at the beginning of the study, to which diets containing 9% or 18% casein were fed ad libitum for a period of 6 weeks. The diet was adjusted after the animals began to eat an average of 10 g/day. Any supplements to the various diets were made at the expense of the carbohydrate. There were no marked growth differences among groups which were fed sucrose, glucose, dextrin or autoclaved potato starch as the source of carbohydrate. The fecal excretion of lysine, valine, histidine and methionine was much higher in animals fed a diet containing potato starch or dextrin than in those containing sucrose or glucose. The amino acids were primarily from endogenous sources, and led the authors to speculate that this effect may have been dependent on changes in the intestinal flora (112).

Schardinger dextrins are a homologous series of cyclic dextrins composed of 6 or more D-glucopyranose units linked by 1-4 bonds as in amylose. The 7 and 7 unit Schardinger dextrins are the most common and are called, respectively, alpha dextrin and beta dextrin. A study using male Wistar rats weighing 185 $\pm$ 50 g was conducted to determine the utilization of 2.5 ml of a 2.5% solution of orally administered Schardinger dextrins. Carbon dioxide excretion was measured by continuous measurement of total labeled CO_2, and, terminally, the distribution of radioactivity in the various organs. The alpha and beta dextrins are metabolized but, initially, at a slower rate than starch. However, after 24 hours the total amounts metabolized are about the same. The distribution of the radioactivity in the animal tissues was similar to that of starch (4).

The metabolic rate and respiratory quotients following the ingestion of dextrin and during fasting were studied in male rats weighing 100 to 220 g. The weight of dextrin for each test meal was determined on the basis of calculations which showed the metabolic rate of male rats to be an average value of 800 calories/square meter of body surface/24 hours. One g of dextrin, by its complete combustion to CO_2 and liquid water, furnishes 4.11 calories. Therefore, to supply 800 calories/square meter of body surface/24 hours, .009734 g of dextrin was fed. To find the total amount of the test meal, the figure .009734 is multiplied by the surface area in square meters. These studies were done under two conditions of light: varying from 3 to 4 days of darkness and 3 to 4 days of light. By maintaining male rats for several days in an environment in which the respiratory gas exchange was determined, the low basal rate of 718 calories/square meter/24 hours was obtained. The hourly averages of the respiratory quotient after a dextrin feeding increased rapidly to 0.744 at the 16th hour and more slowly, with several diurnal variations, to 0.738 at the 43rd hour. The decreases observed were from a high of 0.91 (286).

In an attempt to study the anaphylactoid edema produced in rats by certain dextrins, 0.3 ml was administered i.v. or 0.5 ml intraperitoneally to 10 rats weighing 98 to 104 g. Four different dextrins were used and were identified by A, B, C, and D. Dextrin A was a bactodextrin which was a highly purified product obtained from potato starch. It contained low molecular weight dextrin and was substantially free from dextrose and maltose as well as from high molecular weight starches. Dextrin B was thought to have been similar to Dextrin A. Dextrin C was a potato starch derivative with an average molecular weight of approximately 6,000. Dextrin D was a pyrogen-free tapioca extract which had been lyophilized and contained approximately 2.5% dextrose. The anaphylactoid edema of the snout and paws was evaluated 30 and 60 minutes after the injections and scored on an arbitrary scale of from 0 to 3. Dextrins A and B were completely devoid of any anaphylactoid properties by either route of administration. Dextrins C and D both elicited an anaphylactoid edema which was greater when the substance was injected intraperitoneally. Dextrins C and D, which did elicit the anaphylactoid edema reaction by both routes of administration, are frequently used in the preparation of certain drugs. Dextrin C is used in the preparation of an iron dextrin compound whose trade name is Ferrigen® and Dextrin D is used in the preparation of thorium dioxide known as Thorotrast® (277).

Dextrins which were hydrolyzed for varying periods of time were used to determine the effect on the inhibition of anaphylactoid reaction in the rat. The anaphylactoid activity of intraperitoneally injected dextrin in the rat decreased as the time of hydrolysis increased. After 5 hours of hydrolysis, no reaction was produced in test rats, yet a full response was obtained in non-reactive animals. After 7 hours of hydrolysis, it was inactive intravenously in reactor rats. The biological activity of unhydrolyzed dextrin in both reactor and non-reactor rats was not affected by dialysis. Therefore, the material in the hydrolyzed dextrin which elicited the anaphylactoid reaction in non-reacting animals may be of a relatively low molecular weight. An increase in vascular permeability was induced by the intradermal administration of dextrin in both reactor and non-reactor rats. A dose of 60 micrograms produced the maximal response. The concomitant intradermal injection of glucose inhibited the reaction equally well in both reactor and non-reactor animals (7).

The influence of molecular weight and structure on vascular permeability responses induced by glucose polymer was studied in the hooded Listar and Wistar male rats weighing approximately 200 g. 7 mg/kg of the test material and 0.1 ml of azovan blue dye was administered per injection site. The activity of the synthetic polyglucose of average molecular weight 3,000 was similar to that of a dextrin of molecular weight of 4,000. Dextrin with an average molecular weight of 6,000 was 3 to 4 times more active than the dextran of the same molecular weight. Low molecular weight polymers, that is, synthetic polyglucose and dextrin, were equally active in both reactor and non-reactor rats. It was found that the dose of glucose required to produce 50% inhibition of the response was not significantly different when various molecular weight dextrans were tested. However, very large amounts of glucose were required to antagonize the responses produced by low molecular weight polymers, such as dextran, of average molecular weight 4,000 to 6,000, synthetic polyglucose, and dextrin. Varying degrees of inhibition were obtained from various sugars, and with polyglucose and dextrin the dose of sugars needed for inhibition was increased in proportion to the LD_{50} values for glucose (115).

The effect of partly synthetic diets on the dental caries incidence in the Syrian hamster was studied. It was found that the substitution of dextrin for sucrose in the diet caused a 50% decrease in molar destruction by dental caries (204).

The effect of different dietary carbohydrates on the incidence and extent of dental caries was also studied in the cotton rat. Animals weighing 15 to 20 g were fed various diets containing carbohydrates for a period of 14 weeks. The carbohydrates studied were maltose, glucose, lactose, dextri-maltose, fructose, fine dextrin, coarse dextrin or soluble starch. These carbohydrates were added to the diet at the expense of the sucrose in the ration. The growth rate and mortality were markedly affected by the particle size of the complex carbohydrate. When fine dextrin, soluble starch or fine starch rations were ingested, inferior growth rates were obtained. Seven of the eight animals fed the dextrin ration which contained 18% casein died within 6 weeks. In contrast, coarse dextrin diets afforded excellent growth, in fact, better growth than with any of the other carbohydrates used. The incidence and extent of carious lesions were low in the animals that received coarse or fine dextrin rations. The replacement of 50% sucrose by fine dextrin did not reduce the severity of tooth damage, but the replacement of 75% of the sucrose by fine dextrin afforded partial protection (238).

The occurrence of calcinosis syndrome in the cotton rat was studied in regard to the effect of diet on the ash content of the heart. The animals grew well when fed the basal diet with liver extract. In 7 to 10 weeks, however, their hearts invariably had grossly observable pathological changes and a high ash content of 9 to 19% on a fat moisture-free basis. Substitution of dextrin for sucrose and a low magnesium basal diet resulted in nearly normal growth and a decreased ash content of the heart. Supplementation of the dextrin diet with 10 mg percent α tocopherol did not further decrease the calcinosis (54).

In a later report, the calcinosis syndrome in cotton rats was studied with reference to the effect of diet and age of the animals on the development of the disease and the urinary excretion of various metabolites. Male Sprague-Dawley rats and 3 to 4-week-old cotton rats were fed a diet containing 24% casein, 67% sucrose (and/or substitution of this sucrose by other carbohydrates), 4% modified salt, and 5% corn oil. Urine and blood samples and sections of heart and abdominal muscles were taken from the animals. The creatine excretion level for the cotton rats throughout the period of study was normally low. The data obtained showed that there was either a difference in the heart ash content or in the effect on the he ash content between two litters, thus demonstrating the necessity of having litter mate controls. In the study reviewed in the preceding paragraph, it was found that vitamin-E had no beneficial effect on growth or the ash content of the heart. A concurrent magnesium deficiency increased the severity of the disease, and a reduction of the minerals and other calcium resulted in better growth and a reduced ash content of the heart. In this experiment, it was indicated that the calcinosis was due to excessive intake of Vitamin-D or to an increased requirement of the cotton rat for magnesium or methionine. In another study, the animals were fed cortisone in the ration at an initial level of 3 mg/10 g of ration. Although this level of cortisone was reduced to 1.5 mg. on the 14th day because of the poor growth of the animals, they still failed to grow. It was found that the food consumption and growth increased with increasing levels of magnesium in the ration and decreased when cortisone was the dietary supplement. There was a marked difference in the chloride excretion/ 48 hours, but on the basis of food consumed, there was no difference between the various groups. The phosphorous excretion data was computed on the basis of food consumed; therefore, the animals were divided into two groups, low and high magnesium. It was also found in this study that there was a direct correlation with the terminal severity of the disease which was indicated by the ash content of the heart. In addition to skeletal muscle and heart muscle lesions, the animals fed cortisone showed areas of subcutaneous fat calcification in the thoracic region (55).

In another study in which animals were fed the basal ration with sucrose or dextrin and .08% magnesium, or with sucrose and .05% zinc chloride, the weight gains in the ash and calcium content of cardiac and skeletal muscle confirmed the findings of the first study. It was found that when dextrin replaced the dietary sucrose, the animals showed normal growth despite low levels of magnesium in the diet. The addition of dextrin, or dextrin and magnesium, prevented the decreased appetite which occurred when a low magnesium-sucrose diet was fed. The basal diet supplemented with 5 mg/kg biotin or aureomycin did not prevent or reduce calcinosis. In another study, 6-month-old animals fed the basal diet with dextrin and magnesium were much less susceptible to the development of calcinosis. There was no increase in the ash content of the abdominal muscle. Phosphorous excretion rose abruptly when the synthetic diet was

Single comb white leghorn chickens were used to study the effects of pteroylglumatic acid and an unidentified factor on egg production and hatchability. From the data presented, satisfactory egg production and hatchability was obtained using either sucrose or dextrin as a source of carbohydrate, if liver fraction L or fish solubles and 4.0 mg of pteroylglutamic acid/kg of ration were included in the diet. The data indicates that dextrin favors the intestinal synthesis of some factor in the mature fowl. Evidence indicates that pteroylglutamic acid synthesis in the intestinal tract of the breeding hen is favored by diets containing dextrin as the carbohydrate (58).

The carbohydrate metabolism relative to the effect on the concentration of blood sugar after the feeding of various sugars was studied in human neonates. The g/kg of body weight as a 20% solution was administered to 15 infants, and estimations were made of the blood sugar concentrations during fasting and at 1/2 hour, 1 hour and 2 hours after the test meal. In most of the infants, no rise in blood sugar concentrations occurred after a breast feeding. It was found that dextri-maltose, when compared to the other materials tested in this study, gave most irregular curves following the feeding. The dextri-maltose curve closely paralleled that of the breast-fed infants and was much flatter than the curve found in infants fed another sugar (107).

Twenty-three human chronic ulcerative colitis patients were used to comparatively study dextrose and dextrin tolerance. 1 g/kg of body weight of dextrose or dextrin in 100 to 200 cc of water was administered and samples of blood and urine were collected. After the administration of dextrose, the blood sugar levels rose sharply during the first hour and, during the second hour, fell sharply toward the baseline. By the 4th hour, the lowest value of 15% below the fasting blood level of glucose was reached. The administration of dextrin caused the blood sugar to show a similar pattern but with a much greater rise by the end of the first hour. By the end of the second hour, the drop had not reached as low as was found with the dextrose, at the end of the 4th hour, the level was 5% below fasting level, and at the end of the 5th hour, 13% below fasting. The urine analysis showed the fasting specimens to be negative and revealed reducing substances in only one patient. It was found that the reducing substances were much lower at various time intervals after the administration of dextrin than after the administration of dextrose (208).

The significance of protein sparing effects of dextrin was studied in the male Sprague-Dasley and Wistar rats, 40 to 50 g. The diet was provided ad libitum to cecectimized rats, one group receiving a supplement of sulfasuxidine. It was shown that neither cecectomy nor the feeding of sulfasuxidine suppressed the growth of microorganisms or depressed the growth rate of rats receiving a 9% casein diet containing corn starch. In a nitrogen balance study, rats received either sucrose or dextrin as the carbohydrate. In each series, the percentage of the dietary nitrogen retained was greater in the rats receiving dextrin than in those receiving sucrose. Several diets, which differed only in the types of carbohydrates, were used to study the effect of the type of carbohydrate on the synthesis of B-vitamin in the digestive tract of the rat. In one phase of the experiment, the animals were fed diets containing corn starch for 21 days, and thereafter the feces of each animal were collected and retuqrned to their respective cages for coprophagic consumption. This pattern was also utilized with a sucrose diet. In another segment of this experiment, animals received the diets supplemented by 0.25 g daily of the feces of the animals fed dextrinized corn starch diets. Animals that received diets containing dextrinized starch were denied access to their feces for the first 21 days of the experiment; after this they were fed their own feces daily. The results of growth response were comparable to that found in other animals on a similar regimen who had access to their feces from the beginning of the experiment. In these studies, animals on a dextrinized corn starch diet had enlarged ceca. Animals were cecetimized and were given their own feces as a dietary supplement. During this time, there was a reversal in the animals' weight gain. During the following period, the feces were removed, and, again, the animals lost weight. In another period, the animals' diet was supplemented with bakers yeast, and, again, weight was increased. When the yeast was discontinued, weight declined. It was also demonstrated that the feces from cecectimized animals supplemented with Vitamin B-complex did not support the growth of animals on a B-complex deficient diet. This indicates that it is in the cecum that the feces of animals fed the dextrinized corn starch became capable of supplementing a protein deficient diet (248).

The intestinal synthesis of niacin and folic acid was studied in 21-day-old Sprague-Dawley rats, during a one to two week interval. Phthalysulfathiazole was added to several of the rations as a dietary supplement. The amount of niacin in all studies increased, but the cecum increased in size so that there was relatively no change in the total amount of niacin present. In contrast, the folic acid content was greatly decreased even on a total amount basis. When the level of the sulfur was increased to 4%, niacin and folic acid together could not counteract the effect of the drug (258).

The bile synthesis of B-vitamins was studied in rats to determine the effect of different diets containing starch and dextrin. The rats were then allowed a rest on the laboratory feed. It was found that the total daily nicotinic acid excretion of animals fed a diet containing sucrose was much lower than that of animals fed dextrin or other carbodrates (63).

This study was done to determine the effect of two synthetic rations and a natural diet upon the predominating bacteria and the intestinal tract of strain A mice. Diet 133 contained 30% casein and 45% dextrin. It was supplemented by cystine, Vitamin K, and biotin and folic acid. All diets studied supported growth equally (91).

Single comb white leghorn chickens were used to study the relation of carbohydrate to intestinal synthesis of biotin. The chickens were artificially inseminated weekly, and all eggs laid were marked with the hen's number and the date. A portion of the eggs were analyzed for biotin. Dextrin maintained a higher level of biotin in the egg yolk than did sucrose, and this was associated with a much higher percent hatchability. The results obtained with dextrin, as compared to those obtained with sucrose suggest that there is a marked synthesis of biotin in the intestinal tract and that there is good evidence that the biotin synthesized in the intestinal tract of the pullets fed dextrin was absorbed and deposited in the egg (57).

In another study single comb white leghorns were used to determine the effect of different carbohydrates on the intestinal synthesis of biotin and to determine the influence of various carbohydrates on the numbers and kinds of micro-organisms in the intestinal tract. The carbohydrate sources were sucrose, dextrin, lactose + sucrose and whey + sucrose. At the conclusion of 6 months, 2 chickens were sacrificed from each ration group and 0.5 g of intestinal content was removed from the duodenum and ileum, fecal pouch and colon. It was found that the type of dietary carbohydrate influenced the microflora content of fecal dropping. Dextrin stimulated the development of a considerable number of coloform bacteria as did lactose. Sucrose had a depressive action on fecal coloform. Chickens on a dextrin-containing diet had the greatest number of organisms at all intestinal levels (130).

The effect of carbohydrates on blood amino nitrogen was studied in human subjects ranging from 5 to 81 years of age. A solution of 0.4 g/kg of protein and 1 g/kg of the designated carbohydrate was administered orally in 250 cc of water. A baseline was established and an attempt was made to determine the effect of dextrose, fructose, and sucrose on the index of protein nutrition. In trials with a malto-dextrin product (Mead-Johnson), it was found that this carbohydrate preparation yielded an amino acid index value similar to dextrose, which was found to induce a lower blood amino nitrogen index than fructose (2).

EXHIBIT 1

TABLE II.—CHEMICAL CONSTITUENTS OF 36% TAPIOCA DEXTRIN SOLUTION

	Gm./100
Solids	36.00
Ash	0.06
Chloride	0.02
Sulfate, 0.01 *M*	0.004
	P. P. M.
Potassium	220
Calcium	100
Phosphorus	45
Magnesium	39
Sodium	5–10
Silicon	5–10
Iron	5–10
Boron	0–5
Aluminum	0–5
Copper	0–5
Strontium	0–5
Lead	0–1
Manganese	0–1
Nickel	0–1
Chromium	0–1

DEXTRIN

Bibliography

**Article to be found in summary

*Article to be found in text

DEXTRIN

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